

**510(k) Summary for
Dimension Vista™ CRP Flex® reagent cartridge
Dimension Vista™ Protein 2 Calibrator
Dimension Vista™ Protein 2 Control L and H**

SEP - 6 2006

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K061825

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer: Dade Behring Marburg GmbH
Emil-von-Behring Str. 76
D-35001
Marburg, Germany

Contact Information: Dade Behring Inc.
P.O. Box 6101
Newark, Delaware 19714-6101
Attn: Kathleen Dray-Lyons
Tel: 781-826-4551
Fax: 781-826-2497

Preparation date: August 24, 2006

2. Device Name: Dimension Vista™ C-reactive protein Flex® reagent cartridge (CRP)
Dimension Vista™ Protein 2 Calibrator
Dimension Vista™ Protein 2 Control L
Dimension Vista™ Protein 2 Control H

Classification: Class II; Class II; Class I

Product Code: DCK; JIX; JJY

Panel: Immunology (82) and Clinical Chemistry (75)

3. Identification of the Legally Marketed Device:

Dade Behring CardioPhase® hsCRP - K033908
Dade Behring N Rheumatology Standard SL - K964527
Dade Behring N/T Rheumatology Control SL - K962373

4. **Device Description:**

Dimension Vista™ CRP Flex® reagent cartridge

Polystyrene particles coated with monoclonal antibodies specific to human CRP are aggregated when mixed with samples containing CRP. These aggregates scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the respective protein in the sample. The result is evaluated by comparison with a standard of known concentration.

Dimension Vista™ Protein 2 Calibrator

Protein 2 Calibrator is a liquid human serum based product containing C-reactive protein (CRP).

Dimension Vista™ Protein 2 Control L and H

Protein 2 Control L and H are liquid human serum based products containing C-reactive protein (CRP).

5. **Device Intended Use:**

Dimension Vista™ CRP Flex® reagent cartridge:

The CRP method is an *in vitro* diagnostic test for the quantitative measurement of C-reactive protein (CRP) in human serum and heparinized plasma by means of particle enhanced immunonephelometry on the Dimension Vista™ System. In acute phase response, increased levels of a number of plasma proteins, including C-reactive protein, are observed. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury, and inflammatory disorders.

Dimension Vista™ Protein 2 Calibrator:

Protein 2 Calibrator is an *in vitro* diagnostic product for the calibration of the C-reactive protein (CRP) method on the Dimension Vista™ System.

Dimension Vista™ Protein 2 Control L and H:

Protein 2 Control L and H are for use as assayed intralaboratory quality controls for the assessment of precision and analytical bias in determination of C-reactive protein (CRP) on the Dimension Vista™ System.

6. **Medical device to which equivalence is claimed and comparison information:**

The Dimension Vista™ CRP Flex reagent cartridge, Dimension Vista™ Protein 2 Calibrator and Dimension Vista™ Protein 2 Control L and H are substantially equivalent to the Dade Behring *CardioPhase*® hsCRP assay (K033908) assay, N Rheumatology Standard SL (K964527) and N/T Rheumatology Control SL (K962373), respectively. The Dimension Vista™ CRP assay, like the Dade Behring *CardioPhase*® hsCRP assay is an *in vitro* diagnostic reagent for the quantitative measurement of C-reactive protein (CRP) in human serum and plasma by means of particle enhanced immunonephelometry.

7. **Device Performance Characteristics:**

The Dimension Vista™ CRP assay was compared to the Dade Behring *CardioPhase*® hsCRP assay on the BN ProSpec® System by evaluating serum and plasma samples with concentrations ranging from 3.36 to 182.76 mg/L. Regression analysis of these results yielded the following equation:

Method Comparison Study

	n	Slope	Intercept	Correlation
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				Coefficient
Dimension Vista™ CRP	140	0.985	-0.353	0.997



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Kathleen Dray-Lyons
Regulatory Affairs and Compliance Manager
Dade Behring, Inc.
P.O. Box 6101
Newark, DE 19714

SEP - 6 2006

Re: k061825
Trade/Device Name: Dimension Vista™ CRP Flex® reagent cartridge
Dimension Vista™ Protein 2 Calibrator
Dimension Vista™ Control L
Dimension Vista™ Control H
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: DCN, JIX, JJY
Dated: June 27, 2006
Received: June 28, 2006

Dear Ms. Dray-Lyons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

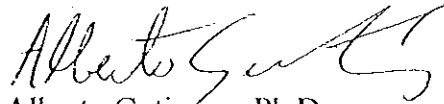
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read 'Alberto Gutierrez', with a stylized flourish at the end.

Alberto Gutierrez, Ph.D.

Director

Division of Chemistry and Toxicology

Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

Device Name: Dimension Vista™ CRP Flex® reagent cartridge
 Dimension Vista™ Protein 2 Calibrator
 Dimension Vista™ Protein 2 Control L
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Dimension Vista™ CRP Flex® reagent cartridge:

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Prescription Use X
(Per 21 CFR 801 Subpart D)

Over-The-Counter-Use
(21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off

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Office of In Vitro Diagnostic Device
Evaluation and Safety

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